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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,742	10/22/2003	Kenneth Jacobs	00766.000091.10	8823

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EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/689,742	JACOBS ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 192, 194 and 195 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 192, 194 and 195 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/25/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicants' amendment and response to the office action dated October 20, 2005, filed on April 25, 2006 is acknowledged. Amendment to the Specification is noted. Claims 192 and 195 have been amended. Therefore, claims 192, 194 and 195 are currently under examination.

Response to Remarks and Arguments

Election/Restriction

Applicants have stated that they affirm their election of Group I, claims 192, 194 and 195 with traverse. Applicants' attention is drawn to the Restriction Requirement in the office Action dated October 20, 2005, where it was stated that during a telephone conversation with Attorney John Magluyan on September 30, 2005 a provisional election was made without traverse to prosecute the invention of group I, claims 192, 194 and 195. However, while addressing the traversal it is noted that the traversal is on the ground(s) that there would not be undue burden in examining the two groups of claims in a single application, therefore, withdrawal of the restriction requirement is requested.

Applicants arguments are not found persuasive because searches only based on nucleic acid and/or polypeptide sequences is not a complete search to examine an invention. In addition to sequence database searches a literature search that includes patent and non-patent literature search completes the entire search. Therefore, rejoinder of claims of Group I to Group II claims would enlarge the search because Class 530 and subclass 350+, which is a large volume class, would be added to the search. Therefore, there would be an additional search burden. Moreover, inventions I and II are unrelated. Group I (claims 192, 194, 195) is drawn to nucleic acid, and do not involve or require use of polypeptide as in Group II (claims 198-201) for its practice. Thus, each of Groups I, II has a mode of operation that is distinct from the other. The polypeptides and polynucleotides are distinct from their structure, and their physical, chemical and biological

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properties, thus one cannot be directly substituted for other. Furthermore, the search burden would be there as indicated by the different classification of each group.

The requirement is still deemed proper and is therefore made FINAL.

Withdrawal of Objections/Rejections.

The objection to the specification is withdrawn in light of amendment to the specification.

The objection to claim 192 (i) is moot in view of cancellation of part (i) of claim 192.

The objection to claim 195 is withdrawn in view of amendment to the claim.

The rejection of claim 192 (h and i) under **35 U.S.C. 101** is moot in view of cancellation of part (h and i) of claim 192.

The rejection of claim 192 (d and e) under **35 U.S.C. 101** is moot in view of cancellation of part (d and e) of claim 192.

The rejection of claim 192 (l) under **35 U.S.C. 101** is moot in view of cancellation of part (l) of claim 192.

The rejection of claim 192 (k, j, l) under **35 U.S.C. 112, first paragraph** is moot in view of cancellation of part (k, j, l) of claim 192s.

The rejection of claims 192, 194 and 195 under **35 U.S.C. 112, second paragraph** is withdrawn in view of amendment to claims.

The rejection of claims 192, 194 and 195 under **35 U.S.C. § 102** is withdrawn in view of the amendments to the continuity data.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”

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Claims 192, 194 and 195 remain/are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polynucleotides are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on pages 87-89 and 177-178 describes clone bn97_1 to which the instant invention relates. Applicants assert (page 178) that the predicted bn97_1 protein demonstrated at least some similarity to sequences of Hepatitis-B virus surface antigen P31 protein for example. Further the specification indicates that the bn97_1 protein also shows some identity to both bovine and human lectin-like receptor for oxidized low-density lipoprotein (LDL). The alignments have not been provided and no percent similarity is disclosed. The specification at page 177 also indicates bn97_1 cDNA was identified as encoding a secreted or or transmembrane protein.

However, the specification fails to provide any sequence with such region, which is a structural characteristic of a Hepatitis-B virus surface antigen P31 protein or bovine and human lectin-like receptor for oxidized low-density lipoprotein; or provides any activity of the polypeptide, which would be similar to the activity of a P31 protein and/or a lectin-like receptor for oxidized low-density lipoprotein. Therefore, only on the basis of some sequence similarity to P31 protein and/or a lectin-like receptor protein, the protein of clone bn97_1 cannot be identified as a member of P31 protein and/or a lectin-like receptor protein family.

Based on the specification (pages 87-89 and 177-178), no biological activity has been set forth for the polypeptide encoded by polynucleotide of clone bn97_1 nor any use for the polynucleotide itself has been provided. However, speculative biological activities have been provided on pages 210-226 of the specification. For example, the use of the polynucleotide for

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further research is described here (page 210). This use is not an acceptable patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed polynucleotides. This situation requires carrying out future research to identify or reasonably confirm a “real world” context of use and therefore do not define specific and substantial utility.

The specification on page 211 states that the polynucleotide and proteins can be used as a nutritional source or supplements. This use is considered to be a “throw away” utility and does not distinguish the claimed polynucleotide over any other polynucleotide. The utility is not specific or substantial.

Other activities that the protein encoded by the polynucleotide may exhibit are listed throughout pages 226-232 of the specification. However, these activities are purely speculative. In summary, the polynucleotides claimed do not have a credible, specific or well-established utility and therefore lacks utility under 35 U.S.C. 101.

Claim 192 (a, b, c) are directed to polynucleotides comprising the sequence of SEQ ID NO: 159 and fragments thereof. As discussed above, based on the specification (pages 87-89 and 177-178) it is unclear what activity the claimed polynucleotides possess, what activity the encoded proteins possess and therefore unclear how a person having skill in the art might use the claimed polynucleotides. It would require undue experimentation for a person having skill in the art to be able to use the claimed polynucleotides. It is *a priori* unpredictable based on the instant disclosure what activity the claimed polynucleotides possess because no correlation has been made between the claimed polynucleotides and a specific activity.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the polynucleotides of SEQ ID NO: 159 or encoding the protein set forth in SEQ ID NO: 160 other than the fact that the protein may be secreted (p. 177). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 160 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified

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biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

In response, applicants traverse the foregoing rejection and assert (page 9 of Response) that the present inventors recognized that the clone bn97_1 is a lectin-like receptor that would share activity with the lectin-like receptor for LDL. In particular, the present inventors recognized that clone bn97_1 would share at least the activity of oxidizing low density lipoproteins, internalizing them into endothelial cells, and destroying them, and thus would play a role in the pathogenesis of atherosclerosis (page 178, lines 22-32 of the specification). In response Applicants' attention is drawn to the 101 rejection in the previous office action and *supra*.

Further while citing *In re Brana* Applicants assert that a post-filing reference can be used to refute any doubts about an asserted utility. The citation is not relevant because nowhere in *In re Brana* it is indicated that a post-filing reference can be used to refute any doubts about an asserted utility.

Applicants submit that the asserted utility is substantiated by the post-filing reference, Eur. J. Immunol., (2000). This reference has been reviewed and Applicants' arguments are fully considered but the arguments are not found persuasive. Applicants assert (see page 9 of Response) that clone bn97_1 has been referred to as "CLEC-1." Eur. J. Immunol. document and sequence alignment has been reviewed. The document indicates that CLEC-1 belongs to the C-type lectin superfamily, however on what basis Applicants submitting that bn97_1 is referred to CLEC-1 is not clear. Regarding sequence alignment, the specification fails to provide any sequence which is a structural characteristic of a CLEC-1 protein that provides any activity of the polypeptide, which would be similar to the activity of the parent protein. Therefore, only on the basis of some sequence similarity the protein of clone bn97_1 cannot be identified as a member of CLEC-1 protein family.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 192, 194 and 195 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

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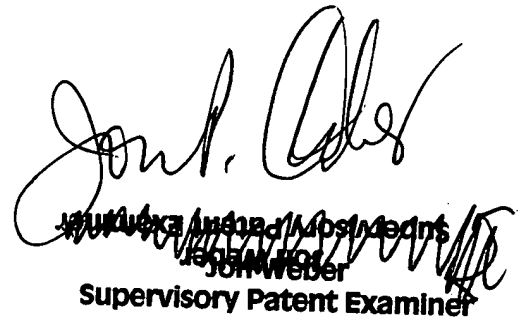
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rita Mitra, Ph.D.

July 1, 2006



Jon Weber
Supervisory Patent Examiner